

determine the continued eligibility of the facility for a certificate or continued compliance with the standards of §900.12;

(4) Has refused a reasonable request of a duly designated FDA inspector, State inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

(5) Has violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to 42 U.S.C. 263b; or

(6) Has failed to comply with prior sanctions imposed by the agency under 42 U.S.C. 263b(h).

(b) FDA may suspend the certificate of a facility before holding a hearing if FDA makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with required standards presents a serious risk to human health;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

(c) If FDA suspends a certificate in accordance with paragraph (b) of this section:

(1) The agency shall provide the facility with an opportunity for an informal hearing under part 16 of this chapter not later than 60 days from the effective date of this suspension;

(2) The suspension shall remain in effect until the agency determines that:

(i) Allegations of violations or misconduct were not substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The facility's certificate is revoked in accordance with paragraph (d) of this section;

(d) After providing a hearing in accordance with paragraph (c)(1) of this section, the agency may revoke the facility's certificate if the agency determines that the facility:

(1) Is unwilling or unable to correct violations that were the basis for suspension; or

(2) Has engaged in fraudulent activity to obtain or continue certification.

§900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.

(a) The appeals procedures described in this section are available only for adverse accreditation or reaccreditation decisions that preclude certification or recertification by FDA. Agency decisions to suspend or revoke certificates that are already in effect will be handled in accordance with §900.14.

(b) Upon learning that a facility has failed to become accredited or reaccredited, FDA will notify the facility that the agency is un-

able to certify that facility without proof of accreditation.

(c) A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body, in accordance with §900.7. A facility must avail itself of the accreditation body's appeal process before requesting reconsideration from FDA.

(d) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeal process is entitled to further appeal in accordance with procedures set forth in this section and in regulations published in 42 CFR part 498.

(1) References to the Health Care Financing Administration (HCFA) in 42 CFR part 498 should be read as the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health, Food and Drug Administration.

(2) References to the Appeals Council of the Social Security Administration in 42 CFR part 498 should be read as references to the Departmental Appeals Board.

(3) In accordance with the procedures set forth in subpart B of 42 CFR part 498, a facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision from DMQRP.

(i) A facility must request reconsideration by DMQRP within 60 days of the accreditation body's adverse appeals decision, at the following address: Division of Mammography Quality and Radiation Programs (HFZ-240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, Attn: Facility Accreditation Review Committee.

(ii) The request for reconsideration shall include three copies of the following records:

(A) The accreditation body's original denial of accreditation.

(B) All information the facility submitted to the accreditation body as part of the appeals process;

(C) A copy of the accreditation body's adverse appeals decision; and

(D) A statement of the basis for the facility's disagreement with the accreditation body's decision.

(iii) DMQRP will conduct its reconsideration in accordance with the procedures set forth in subpart B of 42 CFR part 498.

(4) A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing in accordance with procedures set forth in subpart D of 42 CFR part 498.

(5) Either the facility or FDA may request review of the hearing officer's decision. Such review will be conducted by the Departmental Appeals Board in accordance with subpart E of 42 CFR part 498.

(6) A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

§ 900.16 Appeals of denials of certification.

(a) The appeals procedures described in this section are available only to facilities that are denied certification by FDA after they have been accredited by an approved accreditation body. Appeals for facilities that have failed to become accredited are governed by the procedures set forth in § 900.15.

(b) FDA may deny the application if the agency has reason to believe that:

(1) The facility will not be operated in accordance with standards established under § 900.12;

(2) The facility will not permit inspections or provide access to records or information in a timely fashion; or

(3) The facility has been guilty of misrepresentation in obtaining the accreditation.

(c)(1) If FDA denies an application for certification by a facility that has received accreditation from an approved accreditation body, FDA shall provide the facility with a statement of the grounds on which the denial is based.

(2) A facility that has been denied accreditation may request reconsideration and appeal of FDA's determination in accordance with the applicable provisions of § 900.15(d).

§ 900.17 [Reserved]

§ 900.18 Alternative requirements for § 900.12 quality standards.

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined in paragraph (b) of this section, FDA may approve an alternative to a quality standard under § 900.12, when the agency determines that:

(1) The proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace, and

(2) The proposed alternative:

(i) Is too limited in its applicability to justify an amendment to the standard; or

(ii) Offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the human health; and

(3) The granting of the alternative is in keeping with the purposes of 42 U.S.C. 263b.

(b) *Applicants for alternatives.* (1) Mammography facilities and accreditation bodies may apply for alternatives to the quality standards of § 900.12.

(2) Federal agencies and State governments that are not accreditation bodies may apply for alternatives to the standards of § 900.12(a).

(3) Manufacturers and assemblers of equipment used for mammography may apply for alternatives to the standards of § 900.12(b) and (e).

(c) *Applications for approval of an alternative standard.* An application for approval of an alternative standard or for an amendment or extension of the alternative standard shall be submitted in an original and two copies to the Director, Division of Mammography Quality and Radiation Programs (HFZ-240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. The application for approval of an alternative standard shall include the following information:

(1) Identification of the original standard for which the alternative standard is being proposed and an explanation of why the applicant is proposing the alternative;

(2) A description of the manner in which the alternative is proposed to deviate from the original standard;

(3) A description, supported by data, of the advantages to be derived from such deviation;

(4) An explanation, supported by data, of how such a deviation would ensure equal or greater quality of production, processing, or interpretation of mammograms than the original standard;

(5) The suggested period of time that the proposed alternative standard would be in effect; and

(6) Such other information required by the Director to evaluate and act on the application.

(d) *Ruling on applications.* (1) FDA may approve or deny, in whole or in part, a request for approval of an alternative standard or any amendment or extension thereof, and shall inform the applicant in writing of this action. The written notice shall state the manner in which the requested alternative standard differs from the agency standard and a summary of the reasons for approval or denial of the request. If the request is approved, the written notice shall also include the effective date and the termination date of the approval and a summary of the limitations and conditions attached to the approval and any other information that may be relevant to the approved request. Each approved alternative standard shall be assigned an identifying number.

(2) Notice of an approved request for an alternative standard or any amendment or extension thereof shall be placed in the public docket file in the Dockets Management Branch and may also be in the form of a notice published in the FEDERAL REGISTER. The notice shall state the name of the applicant, a description of the published agency standard, and a description of the approved alternative standard, including limitations and conditions attached to the approval of the alternative standard.